

## REMARKS

In light of the foregoing Amendments and following Remarks, reconsideration and allowance of the above-captioned application are respectfully requested.

Claims 1, 3-8, 10-13, 28, 30, 31, 33, 42-47, 49, 50, 52-54, and 56-76 are currently pending, including independent claims 1, 28, 42, 52, 62, 70, and 76.

The presently pending claims are generally directed to medical devices and methods for using the medical devices. For instance, presently pending independent claim 1 is directed to a medical probe device including an ultrasound transducer assembly. The ultrasound transducer assembly of claim 1 includes a housing that defines a probe guide opening through the housing. The medical probe device of claim 1 also includes a sterilizable seal. The seal is removably co-operable with the transducer assembly and includes a probe guide for receipt into the probe guide opening defined by the housing of the transducer assembly. The probe guide of the seal is such that it provides an unimpeded passageway through the seal. The seal also includes a sleeve that can define a sterile barrier between the housing and an external field. The medical probe device of claim 1 also includes a clamp adapted to secure a probe in the probe guide of the seal.

In the Office Action, claims 1, 2, 28, and 42 were rejected under 35 U.S.C. §102(b) as being anticipated by Kopp, et al. (U.S. Patent No. 4,108,165). The remaining claims were rejected under 35 U.S.C. §103(a) as being unpatentable over Kopp, et al. in view of one or more of Dardel ( U.S. Patent No. 5,341,810), Jingu ( U.S. Patent No. 4,491,137), Kelly, Jr., et al. ( U.S. Patent No. 6,475,152), Lin (U.S. Patent No. 6,261,234), Vilkomerson, et al. (U.S. Patent No. 4,249,539) and Carroll, et al. (U.S. Patent No. 5,119,818).

For instance, in the Office Action, pending claims 7, 9, 10, 22-24 and 55 were rejected under 35 U.S.C. §103(a) as being unpatentable over Kopp, et al. in view of Kelly, Jr., et al.. In particular, with regard to claims 9, 22-24, and 55, it was suggested that Kopp, et al. could be combined with Kelly, Jr., et al., to arrive at a medical biopsy probe device such as that of Kopp, et al. including the sterile clamp of Kelly, Jr., et al. to secure a biopsy device to the ultrasound imaging array.

Applicants respectfully submit that these references could not be combined as suggested. For example, Kopp, et al. is directed to a transducer probe that can fit around a surgical instrument and then be removed from around the instrument after the probe (e.g., the needle) is disposed at the desired position (col. 1, ll. 6-23). According to Kopp, et al., this object of the invention is obtained through utilization of a cap having a stem and slot that can be used with a conventional radially slotted transducer probe such that when the slot of the cap and the slot of the housing are in registration, the needle can be released, and when the slot of the cap and the slot of the housing are out of registration, the needle can be captured (col. 1, ll., 51-64).

Kelly, Jr., et al., discloses, with reference to column 3, lines 1-11 and Figure 3, an outer engagement block 32 including an opening 70 which is adapted to receive a needle guide pin element 72 that includes a pathway 74 for receiving and guiding a biopsy needle. An extension arm 78 extending off of the needle guide pin element enables a user to insert or withdraw the needle guide pin element 72 from within the guide sleeve 70 of the engagement block 32. As can be seen with reference to Figure 4, upon insertion, the needle guide pin element 72 is completely contained within the engagement block 32, but for the extension arm 78 that extends from the side of the engagement block 32. The needle guide pin element 72 is turned within the block 32 to latch it into a closed position and capture a needle therein. No other explanation of the latching device can be found, and as such, Applicants have assumed that upon turning the needle guide pin element 72 via extension arm 78, the needle guide pin element works in cooperation with the block 32 in some fashion that has not been described in the patent to capture the needle.

In order to combine the latching element of Kelly, Jr., et al. with the transducer probe of Kopp, et al., the latching device of Kelly, Jr., et al., including the needle guide pin element 72 with extension arm 78 and the cooperating block 32, would be somehow combined with the cap portion of the device of Kopp, et al. (element 24 on Figure 1 of Kopp, et al.). Upon combining the latching mechanism of Kelly, Jr., et al. with the cap of Kopp, et al., however, the slot of Kopp, et al. would be blocked by the latching mechanism. As the object of Kopp, et al. is to provide an open slot for release of a

needle upon proper rotation of the cap with the transducer probe, the blocking of this slot by the latching mechanism would destroy the function of the device. For at least this reason Applicants submit that Kopp, et al. and Kelly, Jr., et al., can not properly be combined as suggested to arrive at a transducer probe device including a probe guide opening through the transducer probe housing and a clamp.

Applicants respectfully submit that none of the cited references, taken either alone or in any proper combination, disclose or suggest a medical device or a method of using such including a clamping mechanism such as that disclosed in presently pending claims 1, 3-8, 10-13, 42-47, 49, 50, 54, 56, 57, and 70-76, which include a clamp that can be used in conjunction with an ultrasound transducer assembly housing that defines a probe guide opening therethrough. Accordingly, Applicants further submit that these presently pending claims patentably define over the cited references and request allowance of these pending claims.

Applicants further submit that the cited references fail to disclose or suggest certain limitations of the claims as presently presented.

For example, none of the cited references taken alone or in any proper combination disclose or suggest a medical device or a method of using a medical device incorporating the detection of motion of a probe in a probe guide, as is found in certain of the presently pending claims. For example, Vilkomerson, et al. discloses an aspiration needle that can carry a small omnidirectional transducer at the needle point that can sense the imaging ultrasound pulses incident upon the needle transducer following which the location of the needle point can be incorporated into the imaging system based upon the nature of the signal sensed at the needle point transducer. In one embodiment, the point source omnidirectional transducer can also transmit a signal upon sensing an incident pulse. (Col. 2, ll. 7-30.) However, neither this nor any of the other cited references, taken either alone or in any proper combination, disclose a system including a motion detector that detects motion of a probe in a probe guide, as do presently presented claims 12, 13, 46, 47, 52-54, and 59-76. Accordingly, Applicants respectfully submit that these claims patentably define over the cited art and request allowance of these claims.

In addition, none of the cited references, taken alone or in any proper combination disclose or suggest a sterilizable seal including a probe guide that can be received into a probe guide opening defined by an ultrasound transducer housing, wherein the probe guide provides an unimpeded passageway through the seal, and the seal further comprising a sleeve that can substantially surround the ultrasound transducer housing, as is found in pending claims 28, 30, 31, 33, and 57-59. For example, while the probe portion described by Dardel may substantially surround a transducer probe, the device of Dardel does not provide an unimpeded passageway through the disclosed probe portion. For instance, in the described embodiments, the probe portions of Dardel include a capsule wall (reference character 125 in Figures 1, 2 and 3), an exit surface (reference character 225 in Figure 6), or lids (reference characters 14, 15 in Figure 10a) that must be punctured during use of the device. Accordingly, Applicants respectfully submit that these claims patentably define over the cited references and request allowance of these claims.

Moreover, Applicants note that the patentability of the dependent claims does not hinge on the patentability of independent claims 1, 28, 42, 52, 62, 70, and 76. It is believed that these claims possess features that are independently patentable, regardless of the patentability of claims 1, 28, 42, 52, 62, 70, and 76.

It is believed that the present application is in complete condition for allowance and favorable action, therefore, is respectfully requested. Examiner Jaworski is invited and encouraged to telephone the undersigned, however, if any issues remain after consideration of this response.

Please charge any additional fees required by this Amendment to Deposit Account No. 04-1403.

Appl. No. 10/705,784  
Amendment Dated December 20, 2005  
Reply to Office Action of September 22, 2005

Respectfully submitted,

DORITY & MANNING, P.A.

12/20/05  
Date



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